DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4142

September 1, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 – 32

Steven J. Daffer
President and Owner
Sybaritic, Inc.
9220 James Avenue South
Bloomington, Minnesota 55431

Dear Mr. Daffer:

During an inspection of your establishment located in Bloomington, MN, between May 26 and June 10, 2004, our investigator determined that your company manufactures and distributes medical devices such as spa systems, dermabrasion products, and massage/diathermy systems. These are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act in that the methods used in, or the facilities or controls used for, manufacturing, packing, storage, or installation are not in conformance with the Quality System regulations for medical devices, as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820). *Examples* include:

1. Management with executive responsibility has not ensured that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization as required by 21 CFR 820.20. For further explanation, see observation 2 on the Form FDA-483 that was issued to your firm on June 10, 2004. A copy of the Form FDA-483 is enclosed.

2. Procedures to control the design process for your devices were not established, defined, documented, and implemented as required by 21 CFR 820.30(a). See observation 3 on the Form FDA-483 for more information.

3. Complaint handling procedures have not been defined and implemented as required by 21 CFR 820.198(a)(1) to ensure that all complaints are processed in a uniform and timely manner. Also, complaints involving the possible failure of a device to meet any of its specifications were not investigated as required by 21 CFR 820.198(c). See observation 4 on the Form FDA-483 for more information.

4. The procedures for implementing corrective and preventive actions were not established and documented as required by 21 CFR 820.100(a) and 21 CFR 820.100(b). See observation 6 on the Form FDA-483 for more information.

5. Quality audits were not conducted as required by 21 CFR 820.22 to assure that the quality system is effective in fulfilling your quality system objectives. See observation 9 on the Form FDA-483 for more information.

6. Document control procedures were not established as required by 21 CFR 820.40. See observation 12 on the Form FDA-483 for more information.

The inspection also revealed that your firm failed to establish and maintain written Medical Device Reporting procedures as required by 21 CFR 803.17. (See FDA-483 observation 1.) This results in devices being misbranded within the meaning of Section 502(t)(2) of the Act because you failed to comply with a requirement prescribed under Section 519 of the Act.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration (FDA). You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market submissions for Class III devices to which the Quality System/Current Good Manufacturing Practice deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA

without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying system problems necessary to ensure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your response should be sent to Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

During the aforementioned inspection, our investigator collected labeling and promotional material for a number of the medical devices that are manufactured and/or distributed by your firm. Our review of these materials revealed several concerns regarding premarket clearance / approval of your medical devices. We would like to meet with you to discuss these concerns. Please contact Mr. Philips at (612) 758-7133 to schedule a meeting.

Sincerely,

W. Charles Becoat
Director
Minneapolis District

TGP/ccl

Enclosure: FDA-483, 6/10/04